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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,077	03/20/2001	Craig E. Smith	16026-9182-03	1397

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/30/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,077

Applicant(s)

SMITH ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/6/03, 5/19/03, and 8/13/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-21, 86-98, and 101-107 is/are pending in the application.
- 4a) Of the above claim(s) 86-98, 102 and 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21, 101 and 103-106 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☒ Claim(s) 1-11, 13-21, 86-98, and 101-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-11, 13-21, 101, and 103-106) in Paper No. 10, filed 5/19/03, is acknowledged. The traversal is on the ground(s) that the subject matter of both Groups I and II is so closely related that they should be examined in the same application. This is not found persuasive because the distinctness and undue search burden if both Groups were examined together was set forth in the previous office action, mailed 12/12/02, and was not argued with specifically as to why they are closely related. Applicants' traversal argument is therefore not directed to the previously set forth basis for the restriction of Group I from Group II and therefore is moot and thus non-persuasive.

The requirement is still deemed proper and is therefore made FINAL.

VAGUENESS AND INDEFINITENESS

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The antecedent basis for the phrase "the amine with a pK of less than 9" in claim 11 is not clear regarding which amine is meant. Claim 11 depends from claim 1 which contains the slightly different amine containing phrase "an amine with a pK of less than about 9". Is the word "about" missing in the claim 11 phrase to indicate a different amine from the amine in claim 1? Clarification via clearer claim wording is requested.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-21, 101, and 103-106 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,310,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims include common embodiments of pH dependent ion exchange matrices with a silica magnet particle support (instant claims 1-7 and Patent claims 1-18); a plurality of ligands each comprising an aromatic hydrocarbon ring (instant claims 1, 8-10, 103, and 105 and Patent claims 1-4); an amine with pK less than about 9 as well as optionally at least about 4 and up to about 6 (instant claims 1, 11, and 104 and Patent claims 1 and 5); spacer alkyl chain of 2-5 carbon atoms and may be cysteine or alanine (instant claims 13, 14, and 106 and Patent claims 7 and 8); aromatic hydrocarbon linked to the spacer defining histidine or histamine (instant claim 15 and Patent claim 9); linker of 3-8 carbon atoms (instant claim 16 and Patent claim 10); linker alkyl including oxygen, amine, glycidine, or urea (instant claims 17 and 18 and Patent claims 11 and 12); the matrix

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capable of exchanging at a first pH and having a net neutral or negative charge at the desorption pH (instant claims 19 and 21 and Patent claim 13); matrix can be reused (instant claim 21 and Patent claim 18); and the Patent claims are generic regarding the density of ligands attached to the solid support thus deemed inclusive of the broad range of densities in instant claim 101.

Burton et al. (P/N 5,652,348) is cited of interest as disclosing a pH dependent ion exchange matrix with many similarities to the instantly claimed matrix material but does not specifically disclose a low pH for nucleic acid adsorption with a higher pH utilized for desorption of said nucleic acid.

INFORMALITIES

The disclosure is objected to because of the following informalities:

In claim 18, the word "glycidine" appears to be misspelled.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 23, 2003

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER